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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,672	09/23/2003	Samuel I. Stupp	NANO 105 US2 (NU 22074)	1810

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EXAMINER	
NOAKES, SUZANNE MARIE	
ART UNIT	**PAPER NUMBER**
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,672	STUPP ET AL.	
	Examiner	Art Unit	
	Suzanne M. Noakes	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :7-20-07; 4-12-07; 2-16-07;3-23-06; 9-15-05 & 8-15-05.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 13-15 in the reply filed on 19 July 2007 is acknowledged.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 20 July 2007, 12 April 2007, 16 February 2007, 23 March 2006, 15 September 2005 and 15 August 2005 have been considered by the examiner. It is noted that none of the WIPO references cited on the IDS from 16 February 2007 appear to have been submitted by Applicants and thus these references have not been considered. Likewise the WIPO document cited on the IDS from 12 April 2007 does not appear to have been submitted by Applicants and thus has not been considered. See initialed and signed PTO-1449's.

Drawings

3. The informal drawings are not of sufficient quality to permit examination. The details of the figures are often times not distinguishable and lack clarity and these figures are deemed essential to examination. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the

changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Applicant is given a TWO MONTH time period to submit new drawings in compliance with 37 CFR 1.81. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

Specification

Compliance with Sequence Rules

4. The sequence listing, filed in computer readable form (CRF) and paper copy on July 15, 2002, has been received and entered. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to **fully** comply with the requirements of 37 C.F.R. § 1.821 through 1.825; Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

A. The following Figures contain sequences that contain four or more consecutive amino acids without any corresponding SEQ ID NO: **and/or** no reference to any SEQ ID NO: in the Brief Description of the Drawings.

a) In Figure 1, Molecule 1 and 2 both show a peptide amphiphile which contains more than four amino acids in a defined sequence.

B. i) In the specification, p. 9, Table 2, two amino acid sequences are described without a corresponding sequence identifier.

ii) In the specification, p. 2, line 20; p. 3, line 5; p. 7, lines 11 and 13; p. 12, line 4; p. 14, lines 4 and 6 and p. 16, line 19 - two five amino acid peptide sequences are described without a corresponding sequence identifier.

iii) In the specification, p. 10, line 7 and p. 11, line 19 a four amino acid peptide sequence is described with a corresponding sequence identifier.

* If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

Claim Rejections - 35 USC § 112 – 2nd paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim limitations state it is a method of treating a patient with tissue engineered material. However, in order for the claimed invention to work, the administration must occur to a patient in need thereof.

Claim Rejections - 35 USC § 112 – 1st paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description:

6. Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to methods of treating a patient with tissue engineered material by administering to said patient a peptide amphiphile composition, wherein said peptide amphiphile is capable of stimulating or inhibiting a plurality of biological signals at said site and which are also capable of forming a nanofiber network.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc.,

> that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

MPEP § 2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence."

In the instant case, Applicants are describing a huge genus of peptide amphiphile compositions which may vary in structure and size, wherein there is absolutely no structure function correlation. There is only a very vague functional requirement for said peptide amphiphiles which is that is stimulates ***or*** inhibits a *plurality* of biological signals and forms a nanofiber network, however, this functional language does not relate to the structure of the peptide amphiphiles as noted. Thus, one skilled in the art has no idea when looking at any peptide-amphiphile if it actually meets the requirement unless further tests are performed to ascertain the function. As noted above, the Rochester

courts, however, have stated that possession of a claimed *genus may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features.* What is required is a structure function correlation and/or evidence of sufficient number of species which are representative of the broad and diverse genus of peptides-amphiphiles being claimed. As noted, there is a distinct absence in structure-function correlation and in addition, there are only two representative species, Molecules 1 and 2 of Figure 1, for the entire claimed genus. However, these two species are deemed to be broadly representative of the entire diverse and variable genus of peptides and thus Applicants are not in possession of the claimed genus.

Scope of Enablement:

7. Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating a patient in need thereof by administering a composition having Molecule 1 and Molecule 2 (as shown in Figure 1) wherein Molecule 1 stimulates axon outgrowth in neurons and Molecules promotes cell-substrate adhesion in nerve cells, does not reasonably provide enablement for a method of treating a patient in need by administering a plurality of undefined peptide-amphiles which act to stimulate ***or*** inhibit a plurality of any biological signals and also form a nanofiber network. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, the claims are drawn to a huge number of undefined peptide amphiles which are used to treat any undefined disease, condition or state in a patient, who may or may not need the treatment, and wherein the peptide amphiphiles of the composition can have any structure whatsoever, can act on any biological signal that exists (and there are millions of these) which serves either to inhibit *or* stimulate said unspecified biological signal, and wherein said peptide amphiphile composition also can form (but is not required to form, note the “capable of” language) a nanofiber network.

Thus, one who is skilled in the art may not even know where to begin to figure out what kind of peptide composition fulfills all of these or even a part of these requirements. In addition, one of ordinary skill in the art has no idea or way of knowing if a peptide that they have in their possession fulfills these requirements without having to perform an extensive amount of experimentation to find this out. Furthermore, there is also an expectation that one skilled in the art would may necessarily be required make *de novo* peptide amphiphile compositions and then test these to see if they form nanofiber networks, or are capable of doing this, to figure out which of the myriad of possible biological signals said peptide acts upon, whether this is an inhibitory or stimulatory action just to start with because not all 'peptide amphiphiles' form nanofibers or inhibit or stimulate a plurality of biological signals. This is seen as considerable undue experimentation because given the scant information in the specification, which directs one skilled in the art to only two possible peptide amphiphiles of Molecule 1 and Molecule 2, there is nothing else in the way detailing what the fundamental and basic requirements necessary to fulfill the claimed limitations are other than stating that said peptide amphiphiles can possess "an alkyl tail", a "structural peptide" and a "functional peptide" (see p. 9, paragraph 0024). But there is no disclosure of what these structural or functional peptides are or need to be in order to perform the requisite stated limitations in the claims and one skilled in the art has no idea whatsoever if upon constructing a generic peptide such as this if it will form a nanofiber network or if it will stimulate or inhibit any sort of biological signal. While the relative skill in the art is reasonably high there is still a considerable expectation of a serious burden of undue

experimentation because just putting structural peptides with functional peptides along with an alkyl tail is not always sufficient to make nanofiber networks, nor is having two different peptide amphiphiles with opposite charges in the same composition. The claims are so broad that they encompass millions of peptides which may or may not act upon any kind of biological signal whatsoever. Just finding out which biological signal, if any, said peptide amphiphile acts upon is undue experimentation in and of itself because this is not always predictable. Furthermore, as noted, there is only a single peptide amphiphile *composition* in the specification which seems to fulfill the requirements and which is enabled, and said composition contains both Molecule 1 and Molecule 2. There is nothing else but generalities of what is known in the art so that a skilled artisan would necessarily have to use the specification as at most a starting point but would have to navigate through a considerable amount of unpredictable experimentation in order make and use and arrive at the claimed invention.

Thus, when the relevant Wands factors are considered, the claims exceed the scope for which they are enabled.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Kisiday et al. (US 2002/0160471 – cited on Applicants IDS 8-15-07).

Claim 13 is drawn to a method of treating patient with tissue engineered material by administering a peptide-amphiphile composition that is capable of (thus interpreted as it can, but it not required) stimulating or inhibiting a plurality of biological signals and wherein said composition is capable of (same interpretation, it can but it is not required) of forming a nanofiber network.

It is noted that the specification states the following: "Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art." See paragraph 0017, p. 6.

Kisiday et al. teach various peptide amphiphiles, wherein the peptides have alternating hydrophobic and hydrophilic amino acids, are complementary and structurally compatible (see Tables 1-3), and self-assemble into a beta-sheet macroscopic scaffold (e.g. a nanofiber network). The macroscopic scaffold encapsulates living cells, and the encapsulated cells are present in the macroscopic scaffold in a three-dimensional arrangement (see paragraph 0004). It is further taught

that this macroscopic scaffold is administered to mammals for tissue regeneration (see paragraph 0007), wherein the peptide amphiphile scaffold also possesses cell signals such as RGD which act cellular signals to promote proliferation of the encapsulated cells (see paragraph 0040). The peptide amphiphiles also can optionally contain targeting sequences comprising adhesion sites, growth factor binding sites, growth factors, or sequence that provides targeting to a cell, tissue, organ, organ system, or site within an mammal. Thus, the peptides have signals that will affect a plurality of biological signals.

It is noted that the limitation in the claims "capable of stimulation of a plurality of biological signals", the plurality of non-specified signals is met in the instant case because for instance, if a growth factor peptide sequence is incorporated into said peptide or RGD is used, said sequence will affect a cascade of biological signals, some directly and other indirectly. Because there is no distinction in the claim where the plurality of biological signals are required to be directly affected by the peptide amphiphiles themselves (e.g. indirect effects also meet the limitation of the claims), sequences like RGD and those disclosed in Tables 1 and 2 will inherently meet this limitation.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being obvious over Stupp et al. (US 20040001893 – cited on Applicants IDS 2-16-2007).

The applied reference has two common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Stupp et al. teach a peptide amphiphile composition comprising two peptide amphiphiles wherein the first peptide amphiphile possesses a net charge at a physiological sequence and the second peptide amphiphile comprises an opposite charge compared to the first peptide amphiphile at the same pH. Both peptide amphiphiles possess peptide sequences which act as epitopes to stimulate or inhibit

various biological signals and the peptide amphiphiles form a nanofiber network (see for example, claims 28-33). It is specifically noted (see paragraph 0039): "*That the approach of using differently charged amphiphiles can also be utilized to deliver in the self assembling nanofibrous system two or more bioactive molecules, each bearing different charges and this way combining the gelation technology with the delivery of multiple biological signals*." Various specific peptide amphiphiles with opposite charges (e.g. overall net negative and overall net positive) are taught in Table 2. Furthermore, use of this composition for medical and therapeutic administration is contemplated.

Paragraphs 0048-0049 state the following:

Self-assembly and/or gelation under physiological conditions, as induced by the preceding factors, raise numerous implications regarding end use application and effect. Without limitation, with reference to the preceding, a binary or higher PA mixture makes available a sol-gel system for the formation of micellular nanofibers in a aqueous environment at neutral and/or physiological pH conditions. As discussed elsewhere herein, such a combination of two or more PA compounds can be used to assemble nanofibers with a range of residues providing a corresponding variety of concurrent chemical or biological signals for cell adhesion proliferation, differentiation and the like, yielding enhanced properties with regard to tissue engineering or regenerative applications. *Alone, or in conjunction with one or more of the other factors discussed herein, it is contemplated that preferred medical or therapeutic embodiments of such a system or methodology can be implemented upon step-wise introduction and mixing of the subject PA compositions, with in situ gel formation.*

[0049] *Accordingly, such a system can be used in conjunction with a drug, medication or other therapeutic agent, as would be understood by those skilled in the art: the subject drug or therapeutic agent can be provided with or introduced to an appropriate aqueous or polar medium separately or in conjunction with one or more PA compounds.*

> Introduction of a reagent and/or factor induces nanofiber assembly and/or gelation, incorporating such a drug/agent therein, if hydrophobic, or as bound to or sorbed on the surface thereof, if hydrophilic. Disassembly or solubilization of the nanofibrous network or gel can release or deliver the drug/agent as or where required. As would be understood by those skilled in the art made aware of this invention, a range of both hydrophobic and hydrophilic drugs/agents can be utilized herewith. *In particular, with regard to the peptide epitopes thereof, hydrophilic growth factors, co-factors and/or activators can be adsorbed on, delivered with and/or released by the PA compounds/compositions of this invention.*

Example 21 states the following: "One potential application of the peptide-amphiphile self-assembled gels is in the area of tissue engineering, in particular the formation of artificial extracellular matrices and cell delivery systems."

Thus, the clear intention and use of this composition is to use the peptide amphiphile composition which possesses two different peptide amphiphiles which have opposite charges and various biological signals (such as RGD, which is a cell adhesion ligand –see paragraph 0032) or IKVAV which promotes neurite outgrowth in mammalian neurons, or YIGSR plays a related role in neuronal cell-substrate adhension (see paragraph 0040)) wherein said peptides amphiphiles formulate into a nanofiber network, and to use this as a composition specifically designed for tissue engineering.

Stupp et al., however, do not specifically teach the administration of the composition to a patient for tissue engineering. Nonetheless, the intention and suggestion in the prior art is clear, the taught composition is to be used to for tissue engineering. The only way to do this, is for said composition to be administered to a patient. Therefore it would have been obvious to one of ordinary skill in the art at the

time the invention was made to, to administer said composition as taught by Stupp et al. to a patient for the reason of tissue engineering. One would be motivated to do this because Stupp et al. clearly teach that this is the intended use for this composition. Furthermore, one would have a very high expectation of success in administering said composition to a patient in order to provide a tissue engineering composition because using a product which has been designed specifically for this purpose would reasonably be expected to function as it was designed to function, e.g. tissue engineering. It is noted that the recent Supreme Court descision of KSR vs Teleflex Inc., 82 U.S.P.Q.2d 1385 (2007) states that one skilled in the art (in this case a medical expert) has the ability, or common sense, to take elements taught in the prior art and combine them or use them in a way in which each element behaves as it did in the prior art, e.g. the outcome is a predictable result.

Thus, as stated, while Stupp et al. does not specifically teach administering the taught peptide amphiphile composition which has two different charges for each peptide amphiphile, and wherein said peptide amphiphiles carry various components that stimulate or inhibition a plurality of biological signals and forms a nanofiber network, to a patient in a method of tissue engineering, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention to administer said composition to a patient in need thereof in a method of tissue engineering (see Example 21) because the composition is taught that it was designed in part for this purpose and has advantages such as being able to affect more than one biological signal as other peptide amphiphiles compositions do.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes whose telephone number is 571-272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Suzanne M. Noakes
Patent Examiner
Art Unit 1656
01 October 2007